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DEC 0 4 2013

Date: February 11, 2013

Trade Name: Self-Retaining Bicanaliculus Intubation Set II

Common name: Bicanaliculus Intubation

Classification Name: Lacrimal Stents and Intubation Sets

Product Code: OKS

Identification of a Legally Marketed Predicate Device
The Self-Retaining Bicanaliculus Intubation Set II is substantially equivalent to the Self-Retaining Bicanaliculus Intubation Set marketed by FCI Ophthalmics, Inc., 510(k) Premarket Notification Number: K041869, FDA Product Code OKS.

General Description
The Self-Retaining Bicanaliculus Intubation Set II is a bicanalicular intubation device for the treatment of epiphora in adults. The device consists of two silicone anchors connected to a silicone body that is delivered pre-mounted on two guides and packaged with a disposable dilator. The guides facilitate insertion of the Self-Retaining Bicanaliculus Intubation Set II and are completely removed once insertion of the device is complete. The Self-Retaining Bicanaliculus Intubation Set II comes in three different model lengths (25, 30, or 35 mm depending on length of tube required) and is provided as a sterilized product.

Intended Use

Bicanalicular intubation is indicated in treatments of epiphora in adults. Indications for bicanalicular intubation performed with the Self-Retaining Bicanaliculus Stent II are:

- Punctal stenosis
- Canalicular stenosis within the lacrimal drainage system

Comparison of Technological Characteristics

The Self-Retaining Bicanaliculus Intubation Set II and the Self-Retaining Bicanaliculus Intubation Set are identical, or nearly identical, in every respect except for the Self-Retaining Bicanaliculus Intubation Set II is pre-mounted on two metal guides to facilitate insertion of the device. The Self-Retaining Bicanaliculus Intubations Set II is constructed of nearly identical silicone materials as the Self-Retaining Bicanaliculus Intubation Set. Both devices are sterile, single-use and constructed from medical grade materials with well characterized mechanical and biocompatibility properties. Both devices are ethylene oxide sterilized, pre-packaged with a dilator, and provided in similar packaging.

Brief Summary of Non-Clinical Tests and Results

The manufacturing process was validated, demonstrating the capacity of FCI to manufacture the Self-Retaining Bicanaliculus Intubation Set II. Bench top testing was performed on samples before and after sterilization to validate the mechanical characteristics of the silicone anchor, which provides fixation for the device. Test results demonstrated that the silicone anchor was of sufficient tensile strength to resist breakage and device pull-out. Bench top testing was also performed on the finished, sterilized Self-Retaining Bicanaliculus Intubation Set II devices to evaluate the mechanical integrity of the glued portions of the device after the device was inserted and retracted in a ballistic gel model simulating a worst case construct for canalicular anatomy. The self-sealing slit was examined after removal of the devices and, in all cases, the slit was found to be completely sealed. No breakage of the intubation or perforation by the guide was observed in any of the tested devices and the mechanical integrity was unaltered by the testing. The testing demonstrated that the glue bond strength is adequate for the Self-Retaining Bicanaliculus Intubation Set II's intended use. Further bench top testing was performed to evaluate the integrity of the self-sealing slit when the device was placed in a curved position, such as that which would occur if there were an anatomical anomaly that could create a stress on the slit. In all cases, microscopic examination determined that the self-sealing slit was closed after guide removal and that the self-sealing slit remained closed when stressed at a 90° curvature. No breakage or change in the integrity of the slit occurred in any of the devices.

The biocompatibility of the raw materials was tested to the applicable standards and met required specifications. Ethylene oxide sterilization validation studies and package integrity studies were

performed according to the applicable standards; and, the test results support the shelf-life and storage conditions for the device.

From the testing, it can be concluded that all non-clinical test results met the established specifications for the device and the Self-Retaining Bicanaliculus Intubation Set II performs as intended and is constructed of biocompatible materials.

Brief Summary of Clinical Experience

Tabatabaie et al.[1] performed a comparative study of the Self-Retaining Bicanalicular Intubation Set II (SRS) with the Crawford Stent for treating partial or complete canalicular obstruction with epiphora. A total of 21 patients (14 partial, 21 complete obstructions) were treated with the SRS; and 17 patients (11 partial; 6 complete obstructions) were treated with a bicanalicular intubation using the Crawford Stent. Mean duration of stent placement was 3 ±2.6 months (3-6 months). At 1 week postoperatively, 95.2% (20/21 patients) of the SRS-treated patients had a successful outcome compared to 88.2% (15/17 patients) in the Crawford Stent group. Mean duration of follow-up after tube removal was 6.2 ± 1.1 (range 5–8) months. At the last reported visit, 76.2% of patients in the SRS group (12/14 partial; 4/7 complete) had a successful outcome compared to 76.4% (10/11 partial; 3/6 complete) of the Crawford Stent group. No device failures or adverse events were reported for either group.

Patients were excluded in this study if they had previous eyelid and/or lacrimal surgery, a lump overlying or involving the punctum and/or other parts of the tear drainage system, long complete upper lacrimal system obstruction (canaliculi and common canaliculus) on diagnostic probing, or nasolacrimal duct stenosis or obstruction on irrigation testing. The Self-Retaining Bicanaliculus Intubation Set II has never been studied for these conditions.

The Self-Retaining Bicanaliculus Intubation Set II has been sold internationally since 2008, and is currently available in 56 countries worldwide.

Basis of Substantial Equivalence

The Self-Retaining Bicanaliculus Intubation Set II is substantially equivalent to the Self-Retaining Bicanaliculus Intubation Set in material, intended use, basic design concept, dimensions, sterilization methods, and biocompatibility. Both devices are manufactured by (or for) FCI SAS and distributed in the U.S.A. by FCI Ophthalmics, Inc.

[1] Tabatabaie SZ, Rajabi MT, Rajabi MB, Eshraghi B. Randomized study comparing the efficacy of a self-retaining bicanaliculus intubation stent with Crawford intubation in patients with canalicular obstruction. Clinical Ophthalmology 2012:6, 5–8.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 4, 2013

France Chirurgie Instrumentation (FCI SAS)
% Barbara S. Fant, Pharm.D.
President, CRC Inc.
3308 Jefferson Avenue
Cincinnati, OH 45220

Re: K130375
Trade/Device Name: Self-Retaining Bicanaliculus Intubation Set II
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: OKS
Dated: October 28, 2013
Received: October 29, 2013

Dear Dr. Fant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K130375

Device Name: Self-Retaining Bicanaliculus Intubation Set II

Indications for Use:

Bicanalicular intubation is indicated in treatments of epiphora in adults. Indications for bicanalicular intubation performed with the Self-Retaining Bicanaliculus Stent II are:

- Punctal stenosis
- Canalicular stenosis within the lacrimal drainage system

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tieuvi H. Nguyen
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